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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/647,777  | 12/29/2000  | Hiroynki Morimoto    | 02500.000006.       | 3913             |
| 5514 7590 01/18/2011<br>FITZPATRICK CELLA HARPER & SCINTO<br>1290 Avenue of the Americas<br>NEW YORK, NY 10104-3800 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| TRAN, SUSAN T   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1615  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/647,777

**Applicant(s)**

MORIMOTO ET AL.

**Examiner**

S. TRAN

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-123 is/are pending in the application.

4a) Of the above claim(s) 110 and 111 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☐ Claim(s) 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91, 99-109 and 112-123 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-943)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/04/10 has been entered.

### ***Election/Restrictions***

Newly submitted claims 110 and 111 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 110 is directed to a method for maintaining a function of a compressed tablet that is distinct from a method for preparing a tablet, which does not require any function of the tablet.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 110 and 111 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91, 99-109 and 112-123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While the present specification at page 51 discloses a tableting pressure of  $0.7 \text{ ton/cm}^2$ , it appears that the present specification does not provide adequate support for tableting pressure of “0.7 to 1.3 ton/cm<sup>2n</sup>” and “from 0.7 to 1.0 ton/ cm<sup>2n</sup>”.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91, 99-109 and 112-123 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,964,779 ('779) in view of Andoh et al. US 5,576,021 ('021). USPN '779 discloses a method for producing compressed tablets, comprising: selecting powdered or granular material comprising an active compound which is denaturalized or inactivated when compressed at a pressure greater than or equal to 1 ton/cm<sup>2</sup>, providing a spraying chamber housing a punch and a die, generating pulsating vibration air, spraying, within a spraying chamber, a lubricant admixed with said pulsating vibration air to apply the lubricant on surfaces of said punch

and die, mixing said powdered or granular material with a diluting agent to make a molding material, said molding material not containing said lubricant, and compressing said molding material using said lubricated punch and said lubricated die surfaces at a pressure less than 1 ton/cm<sup>2</sup> to produce compressed tablets, wherein sprayed lubricant is incorporated in said tablets at an amount not less than 0.0001 weight percent and not greater than 0.2 weight percent. Stearate acid metal salt is found in claim 5.

USPN '779 does not expressly teach that the granule is coated with a film layer. USPN '021 teaches a multi-granule tablet comprising sustained release granules coated with a film-forming composition. See abstract; column 2, lines 15-42; Examples; and claims. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the sustained release granule before compressing into tablet. This is because USPN '021 teaches that "by coating the outer surfaces of sustained-release granules with a formulation aid and forming protective coating films thereon, the discreteness of each granule can be enhanced so that their agglomeration upon compression-forming or their deformation or destruction can be avoided". See column 2, lines 38-42.

### ***Response to Arguments***

Applicant's arguments filed 11/04/10 have been fully considered but they are not persuasive.

Applicant argues that Experiments 3 and 4 (specification pages 62-63) press tablets at 500, 1000 and 1500 kg/punch (page 62, lines 15-17 and page 63, lines 12-

14). The punch is as used in invention 1 (page 63, lines 15-16), e.g., having a 7 mm diameter punch and die set (page 46, line 25 to page 46, line 1). As is well-understood then, 500kg/punch is 1.299 ton/cm<sup>2</sup>. Therefore, the Examiner's comment that there are no values between 0.7 ton/cm<sup>2</sup> and 1.3 ton/cm<sup>2</sup> is incorrect. In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

However, in response to Applicant's arguments, the Examiner notes that the value calculated from 500 kg/punch resulted in 1.299 ton/cm<sup>2</sup> is being rounded to 1.3 ton/cm<sup>2</sup>. See Applicant's Remarks filed 12/14/09 at page 11. Hence, this is not a value that shows support for a tablet pressure that falls between 0.7 to 1.3 ton/cm<sup>2</sup>. Further, it is noted that Tablet 2 shows tablet pressure at 0.7 ton/cm, and the rest of the Examples show tablet pressure at 500 kg/punch, 1000 kg/punch, and 1500 kg/punch. None of the Examples show values between 0.7-1.3 ton/cm<sup>2</sup>. Accordingly, the 112, first paragraph rejection is maintained.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1615